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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,058	04/02/2004	John E. Baker	BA-32448(1)	2664

22202 7590 04/10/2006

WHYTE HIRSCHBOECK DUDEK S C  
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EXAMINER
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NOAKES, SUZANNE MARIE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/817,058

Applicant(s)

BAKER ET AL.

Examiner

Suzanne M. Noakes, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-18,24-29,31 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-18,24-29,31 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Applicants remarks on 11 January 2006 indicate that claim 1 has been cancelled, it appears that actually claim 2 has been cancelled and 1 is still pending. Applicants have cancelled claims 2, 4, 19-21, 23 and 30. The pending claims are 1, 3, 5-18, 24-29, 31 and 47.

### ***Withdrawal of Objections and Rejections***

2. The objection to the specification (Section 5 of previous Office action) is hereby withdrawn.

3. The rejection of claim 47 under 35 U.S.C. 112 2<sup>nd</sup> paragraph (Section 7 of the previous Office action) is hereby withdrawn.

4. The rejection of claims 25 and 26 under 35 U.S.C. 112 1<sup>st</sup> paragraph (Section 9 of the previous Office action) is hereby withdrawn.

### ***Maintained Objections and Rejections***

#### ***Claim Rejections - 35 USC § 102(e)***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 3, 5-18, 24-29, 31 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Brines et al. (US 6,531,121). The details of the rejection can be found in the previous Office action, pp. 4-8, Section 10).

***Claim Rejections - 35 USC § 102(e)/103***

7. Claims 3-5, 17, 24-26 and 28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brines et al. (US 6,531,121). The details of the rejection can be found in the previous Office action, pp.8-12, Section 11.

***Response to Arguments***

8. Applicant's arguments filed 11 January 2006 have been fully considered but they are not persuasive.

The rejections at issue are those under 35 U.S.C. 102(e) and 102(e)/103 as anticipated, or in the alternative obvious over Brines et al. (US 6,531,121).

Applicants have amended the claims to more clearly state their claimed invention and these include: administration as a single treatment, given at a defined time (as outlined in claim 1), with the achievement of a certain blood concentration level at a defined time limit post administration. Applicants main arguments for why Brines et al. do not anticipate the claimed invention is two fold.

First, it is argued that Brines et al. teach administration of more than a single treatment, and this is highlighted by Example 3 (which was cited in the previous Office action) that administration occurs 24 hours prior and again immediately before an ischemic event). However, the examiner wishes to point out that the teachings of Brines et al. is not merely limited to that of Example 3. In fact it is repeatedly echoed throughout the patent that administration may be dosed to the patient in need thereof

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using an amount, duration and frequency of dosing which achieves the desired enhancement or protection (see column 4, lines 26-37). Thus Brines et al. is teaching that it would be obvious to one skilled in the art to take their claimed invention and adapt it as needed. Whether this is a single dose or multiple doses is not the crux of their invention and teaching, they provide the exact tools to prevent and treat an ischemic event and equip a skilled artisan, in this case a certified nurse or M.D. to be able to figure out what constitutes an effective dose. This notwithstanding, the example given for Example 3 does clearly administer EPO in a single dose 24 hours prior and another single dose immediately before the ischemic event. This *still* anticipates the claims, because whatever steps and methods recited after the preamble are not strictly limited to those steps because Applicants have chosen to use open comprising language. Thus multiple steps and multiple doses, such as that taught in Example 3 of Brines et al., necessarily anticipates the claims.

The second argument Applicants assert is that Brines et al. does not teach serum levels which are achieved 1-35 minutes after administration. Instead, they teach that these serum levels are achieved 1-10 hours post administration. The examiner acknowledges that this is what Brines et al. state, however, the examiner has stated that inherently, with everything being equal, that is the exact same concentrations of EPO that is administered is taught by Brines et al. and by Applicants, that the desired serum concentration level which is achieved within 1-35 minutes will be inherent and necessarily achieved in the Brines et al. method. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the

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prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Furthermore, a skilled artisan, such as Brines et al. need not have even recognized that this serum level was achievable in the time now claimed by Applicants, because there is no requirement that a person of ordinary skill in the art needs to recognize the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Thus, it is believed that Brines et al. does in fact teach, *prima facie and* inherently, each and every claimed limitation presented by Applicants.

### **Conclusion**

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

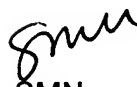
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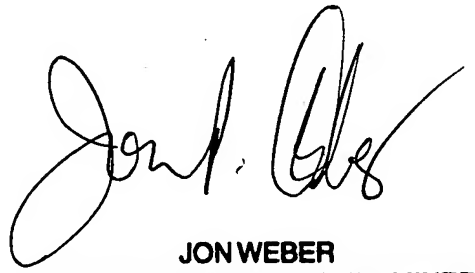
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SMN  
29 March 2006

  
**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**